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/Denise G. Bachtel/
Denise G. Bachtel

January 30, 2009
Date

AVERP3447USA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: :
Sjoerd Johannes van Driesten : Group Art Unit: 1794
Serial No: 10/796,758 : Examiner: Thao T. Tran
Filed: March 9, 2004 : Confirmation No: 4363
**For: REUSABLE CLOSURES FOR PACKAGES AND
METHODS OF MAKING AND USING THE SAME**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICANT'S BRIEF ON APPEAL

Dear Sir:

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This Appeal Brief is submitted in the above-identified application in response to the Final Office Action mailed July 10, 2008. Appellant's Notice of Appeal was filed on September 30, 2008. A petition for a two (2) month extension of time is enclosed. Accordingly, Appellant's Appeal Brief is timely filed.

I. REAL PARTY IN INTEREST

The real party in interest is Avery Dennison Corporation, 150 North Orange Grove Boulevard, Pasadena, California 91103, the assignee of the above-captioned application.

II. RELATED APPEALS AND INTERFERENCES

Appellant is aware of no related appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

III. STATUS OF CLAIMS

Claims 1-11, 19-20, 41, 43 and 45-48 are pending in the application. Claims 12-18, 21-40, 42 and 44 have been canceled. Claims 1-11, 19-20, 41, 43 and 45-48 stand finally rejected and are the subject of the present Appeal.

IV. STATUS OF AMENDMENTS

A response under 37 C.F.R. §1.116 was filed on September 30, 2008. The Examiner entered the response in an Advisory Action mailed on November 3, 2008, and maintained the final rejection as set forth in the Office Action mailed July 10, 2008.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

In an embodiment of the invention described in independent claim 1, there is provided An adhesive article comprising (a) a moisture resistant substrate having a first and second surface, (b) a removable and resealable adhesive adhered to at least a first portion of the first surface of the substrate, and (c) a permanent adhesive adhered to at least a second portion of the first surface of the substrate. The removable adhesive is removable and resealable in the presence of moisture from refrigerated or frozen food

packaging environments and has a Moist Loop Test result of at least about 0.8 N/25mm at a test plate temperature of 5°C.

In an embodiment of the invention described in independent claim 41, there is provided a sheet of adhesive closures comprising a carrier sheet having a release surface; and a plurality of adhesive articles releasably adhered to the release surface of the sheet. Each article comprises (a) a moisture resistant substrate having a first and second surface, (b) a removable and resealable adhesive adhered to at least a first portion of the first surface of the substrate, and (c) a permanent adhesive adhered to at least a second portion of the first surface of the substrate. The removable adhesive is removable and resealable in the presence of moisture from refrigerated or frozen food packaging environments and has a Moist Loop Test result of at least about 0.8 N/25mm at a test plate temperature of 5°C.

In another embodiment of the invention described in independent claim 43, there is provided a roll of adhesive closures comprising a wound carrier having a release surface; and a plurality of adhesive articles releasably adhered to the release surface of wound carrier. Each article comprises (a) a moisture resistant substrate having a first and second surface, (b) a removable and resealable adhesive adhered to at least a first portion of the first surface of the substrate, and (c) a permanent adhesive adhered to at least a second portion of the first surface of the substrate. The removable adhesive is removable and resealable in the presence of moisture from refrigerated or frozen food packaging environments and has a Moist Loop Test result of at least about 0.8 N/25mm at a test plate temperature of 5°C.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-4, 18, 41, 43, and 45 are unpatentable under 35 U.S.C. §102(b), as being anticipated by Bane (US 5,366,087).

B. Whether claims 1, 5, 8, 11, 19-20, 41, 43, and 45-47 are unpatentable under 35 U.S.C. §102(b), as being anticipated by McClintock (US 5,217,307).

C. Whether claims 5-7 are unpatentable under 35 U.S.C. § 103(a) based on Bane (US 5,366,087) in view of Freedman et al. (US 4,543,139).

D. Whether claims 2-4, and 6-7 are unpatentable under 35 U.S.C. § 103(a) based on McClintock (US 5,217,307) in view of Freedman et al. (US 4,543,139).

E. Whether claims 5-11, 19-20, and 46-48 are unpatentable under 35 U.S.C. § 103(a) based on Bane (US 5,366,087) in view of van Driesten et al. (WO 00/46316).

F. Whether claims 2-4, 6-7, and 9-10 are unpatentable under 35 U.S.C. § 103(a) based on McClintock (US 5,217,307) in view of van Driesten et al. (WO 00/46316).

VII. ARGUMENT

A. The rejection of claims 1-4, 18, 41, 43, and 45 under 35 U.S.C. §102(b).

The Examiner's Rejection:

Claims 1-4, 18, 41, 43, and 45 have been rejected under 35 U.S.C. §102(b) as being anticipated by Bane (US 5,366,087).

The Examiner contends that

Bane discloses a label to reseal a package, comprising a substrate 11 of paper that can be coated with a thermally sensitive coating 12 having a perforated line, are coatings 14 and 15 of adhesives. Coating 14 is a permanent pressure sensitive and hotmelt (heat sensitive) adhesive and coating 15 is a repositionable adhesive (removable and resealable) (see Figs. 1-4; paragraph bridging col. 2-3; paragraph bridging col. 3-4). A release liner 16 covers the coatings 14 and 15, or coating 12 so as to provide a roll of such labels (see col. 3, ln. 8-23).

Although the reference does not specifically teach the substrate to be moisture resistant, the adhesive to be removable and resealable in the presence of moisture from food packaging environments, or its Moist Loop Test result, since the reference teaches the same components in the laminate, the laminate would inherently have all the same properties as presently claimed.

(Final Office Action, July 10, 2008, Pages 2-3.)

The Examiner also contends that “since Base teaches the adhesives as claimed, they would inherently have the same properties as claimed.” (Final Office Action, July 10, 2008, Page 7.) The Examiner further stated that Applicants should “include the chemical or structural elements to impart these properties in order to be patentably distinct over the prior art.” (Id.) The Examiner concluded by stating that Bane anticipates the claims because the claims “recite[] the permanent and repositional adhesives in general.” (Id.)

Appellant’s Response

A. The Examiner Failed to Establish Inherency

The Examiner’s rejection of claims 1-4, 18, 41, 43, and 45 under 35 U.S.C. § 102(b) as being anticipated by Bane is based on inherency. A reference fails to anticipate a claim unless the reference discloses each and every element as set forth in the claim. (MPEP § 2131.) The reference must show the identical invention in as complete detail as is contained in the claim. (Id.) Each feature must be found either expressly or inherently in the reference. But “anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation.” (*Trascleen Corp. v. Bridgewood Serv., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002).)

To establish inherency the Examiner bears the initial burden to provide a basis in fact and/or technical reasoning to support a position that the allegedly inherent feature necessarily flows from the cited reference. (*Ex parte Levy*, 14 USPQ 2d 1461, 1464 (BPAI 1990); MPEP § 2112(IV).) The Examiner must show that the missing descriptive matter (i) is necessarily present in the thing described in the reference, and (ii) would be recognized by persons skilled in the art as being necessarily present. (*In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); MPEP § 2112(IV).) Further, inherency cannot be established by mere possibilities or probabilities. (Id.) The fact that a characteristic may be present is not sufficient to establish inherency. (Id.)

The Examiner admitted that Bane fails to disclose each and every element as set forth in the claims. Specifically, the Examiner admitted that Bane does not specifically teach the substrate to be moisture resistant, the adhesive to be removable and

resealable in the presence of moisture from food packaging environments, or its Moist Loop test result ..." (See, e.g., Final Office Action, page 3.) To argue inherency, the Examiner only summarily stated that (i) Bane teaches the components of the laminate and, therefore, inherently teach the other features of the claims, and (ii) Bane anticipates the claims because the claims "recite[] the permanent and repositional adhesives in general." These, however, are merely conclusory statements that do not provide a basis in fact or cogent technical reasoning to support a conclusion that Bane inherently teaches the missing features. And the Examiner has not provided any objective evidence to demonstrate that the generic disclosure of a repositional adhesive necessarily means that repositional adhesives are removable or resealable in the presence of moisture and/or have a Moist Loop Test result of at least 0.8 N/25mm. Such conclusory statements, absent any other objective evidence, do not satisfy the Examiner's initial burden of establishing inherency.

Contrary to the Examiner's allegation, Bane does not teach "the same components" or the same adhesives in the laminate. Bane simply discloses that the adhesives 14 and 15 may be selected from a wide variety of "conventional permanent and repositional adhesives." (Bane, column 3, line 57.) This general disclosure, however, does not provide a reasonable basis in fact or evidence that all conventional repositional adhesives necessarily have a Moist Loop Tack of at least about 0.8 N/25mm or are removable and resealable in the presence of moisture from refrigerated or frozen food packaging environments as recited in the claims. Moreover, disclosing specific examples of adhesives does not provide a reasonable basis in fact that such materials necessarily have a particular property.

Even if it is possible that a conventional repositional adhesive might have a Moist Loop Tack of 0.8 N/25mm at 5°C, mere possibilities are not sufficient to establish inherency. Rather, to establish inherency, the Examiner must establish that it is necessary, in all cases, for "conventional" adhesives to have the recited properties. As described above, the Examiner failed to make such a showing.

For at least these reasons, the rejection should be reversed. A recent Board decision further supports Appellant's position.

In *Ex parte Whalen*, 89 USPQ2d 1078 (BPAI 2008) (Exhibit A), the Board of Patent Appeals and Interferences reversed the Examiner's anticipation and obviousness rejections based on inherency. In *Whalen*, the claims were directed to a composition for embolizing an aneurysm. The claims recited that the composition comprised a biocompatible polymer, a biocompatible contrast agent, and a biocompatible solvent, and required that the composition have a viscosity of at least about 150 cST at 40°C. (*Whalen*, 89 USPQ2d at 1079).

The Examiner rejected *Whalen's* claims as being anticipated by prior art that disclosed compositions with similar components to those recited in the claims, but did not disclose the claimed viscosity. (Id. at 1082.) The Examiner contended that the references inherently disclosed the claimed viscosity because the disclosed compositions comprise similar components in overlapping concentration ranges. (Id.)

The Board reversed the rejections because the Examiner did not provide evidence or scientific reasoning to show that the compositions disclosed in the references inherently possess the same viscosity. (Id. at 1083.) The Board found that the Examiner's reasoning that the prior art's disclosure of similar components inherently possesses the claimed viscosity amounted to no more than a possibility that the prior art disclosure might have such a viscosity. But that mere possibility could not support a finding of inherent anticipation. (Id.)

This case is analogous to *Whalen*. Similar to *Whalen*, the Examiner has done no more than argue that Bane (or McClintock, which is discussed below) teach the same components and, therefore, teach the claimed properties recited in Appellant's claims. But, just as in *Whalen*, the Examiner has not provided any evidence or scientific reasoning to support that position. As discussed above, the Examiner has not provided evidence or scientific reasoning to show that Bane's components necessarily are removable and resealable in the presence of moisture or have a Moist Loop Tack of at least 0.8 N/25mm. Thus, similar to the rejections in *Whalen*, the Examiner's rejections based on Bane (or McClintock discussed below) should be reversed.

B. The Examiner Failed to Establish Inherency and Improperly Shifts the Burden Under § 102

Applicant does not believe it is necessary, as argued by the Examiner, to include chemical or structural elements that impart the claimed properties in order to establish patentability. The Examiner has provided no basis for this requirement. The Examiner bears the initial burden to establish that a reference shows each and every element recited in the claims either expressly or inherently. When the rejection is based on inherency, that burden is not discharged or shifted unless the Examiner provides evidence or scientific reasoning to establish the reasonableness of the Examiner's belief that a characteristic is an inherent feature of the prior art. (*Ex parte Skinner*, 2 USPQ2d 1788, 1789 (BPAI 1986).) As described above, the Examiner failed to satisfy his initial burden to establish inherency.

Moreover, the claims sufficiently describe the structure of the adhesive article and sufficiently describe what features are required of the removable adhesive. The claimed article as a whole distinguishes from the art cited by the Examiner because the art does not show every claim limitation either expressly or inherently. That is, the claims are patentable over the art because Bane (and McClintock) fail to show — and the Examiner failed to establish that Bane or McClintock (see below) inherently teach — an adhesive article that includes a removable adhesive that is removable and resealable and has a Moist Loop Test result of at least about 0.8 N/25mm at a test plate temperature of 5°C. It is through Applicant's discovery of providing an article that employs an adhesive having these properties that the desired advantages of the article are achieved.

Additionally, Applicant submits the Examiner fails to apply the correct standard for anticipation. A reference fails to anticipate a claim unless the reference discloses each and every element as set forth in the claim. (MPEP § 2131.) Again, the Examiner has not made this showing. By stating that the claims recite “the permanent and repositional adhesives **in general**, thus what is taught by Bane would anticipate the claims” (emphasis added), the Examiner ignores or disregards claim limitations. In particular, the Examiner disregards the limitations that the removable adhesive is removable or resealable in the presence of moisture and has a Moist Loop Test result of

at least about 0.8 N/25 mm at a test plate temperature of 5°C. This is improper because the USPTO “must consider all claim limitations when determining patentability of an invention over the prior art.” (*In re Lowry*, 32 F. 3d. 1579, 1582 (Fed. Cir. 1994).) That is, “[c]laim limitations defining the subject matter of the invention are never disregarded.” (*In re Sabatino*, 480 F.2d 911, 913 (CCPA 1973).)

As such, the Examiner’s arguments in the Final Office Action improperly shift the burden to prove the claims are patentable, when the Examiner failed to satisfy his burden of establishing that the cited reference(s) anticipate the claims.

Bane fails to anticipate the claims because it fails to either expressly or inherently teach all the elements as recited in the claims. At the least, the Examiner has not met the initial burden of demonstrating that Bane necessarily teaches certain features such as a moisture resistant substrate or a removable adhesive having a Moist Loop Tack of at least 0.8N/25mm. Applicant respectfully requests that the rejection of claims 1-4, 18, 41, 43, and 45 under § 102(b) be reversed.

B. The rejection of claims 1, 5, 8, 11, 19-20, 41, 43, and 45-47 under 35 U.S.C. §102(b).

The Examiner’s Rejection:

Claims 1, 5, 8, 11, 19-20, 41, 43, and 45-47 have been rejected under 35 U.S.C. §102(b) as being anticipated by McClintock (US 5,217,307).

The Examiner contends that

McClintock discloses an adhesive article, comprising a substrate (face stock 11), a removable and resealable adhesive 18B adhered to at least a first portion of the first surface of the substrate, a permanent adhesive 18A adhered to at least a second portion of the first surface of the substrate, a release member 16 with a release coat 20 (see Fig. 2 & 9). Fig. 9 shows web W carries a plurality of the adhesive articles.

The face stock can be made of polyester. The release coat is silicone. The removable or permanent adhesive is pressure sensitive of acrylic or rubber-based (see col. 7, ln. 35-43).

Although the reference does not specifically teach the substrate to be moisture resistant, the adhesive to be removable and resealable in the presence of moisture from food packaging environments, or its Moist Loop Test result, since the reference teaches the same components in the laminate, the laminate would inherently have all the same properties as presently claimed.
(Final Office Action, July 10, 2008, Page 3.)

Appellant's Response

The Examiner's rejection of the claims as being anticipated by McClintock is also based on inherency. Applicant incorporates the arguments and discussion previously made with respect to the rejections based on Bane.

As was the case with rejection based on Bane, the Examiner failed to establish that McClintock inherently discloses the claimed features. McClintock discloses that the adhesive may be "any of the well known types such as pressure sensitive adhesive of the acrylic removable or permanent type or emulsion permanent or removable rubber based permanent and emulsion removable." (Col. 7, lines 38-43.) Similar to the rejections based on Bane, the Examiner only provides conclusory statements and fails to provide any evidence or cogent technical reasoning or objective to support a finding of inherency. In particular, the Examiner fails to demonstrate that McClintock's mere disclosure of an acrylic removable adhesive or other type of removable adhesive teaches that all such materials necessarily have a Moist Loop Tack of at least 0.8 N/25 mm.

McClintock actually supports Applicant's argument that the Examiner failed to establish inherency (as it pertains to the rejections under either Bane or McClintock). McClintock discloses that the adhesive may be "any of the well known types such as pressure sensitive adhesive of the acrylic removable or permanent type or emulsion permanent or removable rubber based permanent and emulsion removable." (Col. 7, lines 38-43 (emphasis added).) This statement illustrates that an adhesive based on a particular class of polymer, e.g., acrylic, may be provided as a permanent or a removable adhesive. This shows that a person skilled in the art would understand that adhesive materials may be formed from the same class of materials (e.g., acrylics) but exhibit or be provided with different adhesive properties. That is, a particular class of material does not necessarily exhibit or possess a certain property or characteristic such as, for example, a particular adhesive strength or tack.

Therefore, for at least these reasons, the Examiner failed to satisfy his initial burden to establish inherency. Applicant requests that the rejection of claims 1, 5, 8, 11, 19-20, 41, and 43 be reversed.

C. The rejection of claims 5-7 under 35 U.S.C. §103(a).

The Examiner's Rejection:

Claims 5-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bane (US 5,366,087) as applied to claim 1, and further in view of Freedman et al. (US 4,543,139).

Regarding claims 5-7, the Examiner contends that

Bane does not teach the substrate to be the polymer as recited in the instant claims.

Freedman teaches an adhesive tape for use on a substrate that is a polymer such as polypropylene and polyesters including polyethylene terephthalate (see col. 4, ln. 57-58; col. 5, ln. 11-20).

Therefore, it would have been obvious to one of ordinary skill in the art to have employed the substrate, as taught by Freeman, in the adhesive article of Bane. Since Freeman teaches the use of a substrate made of polypropylene and polyethylene terephthalate as well as polymer-coated paper as alternatives of each other, the use of one or another would have been dependent upon user's preference and intended use.

Appellant's Response

The Examiner bears the burden to establish a *prima facie* case of obviousness. Obviousness requires a suggestion of all the elements of a claim and an articulated reason why a person skilled in the art would have combined the elements in the way that is being claimed. (*Ex parte Alexander*, USPQ2d 1120, 1122 (BPAI 2007) (citing *CFMT, Inc. v. Yieldup Int'l. Corp.*, 68 USPQ2d 1940 (Fed. Cir. 2003) and *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 18741 (2007).)

Claims 5 and 7 depend from claim 1 and therefore include all the features of claim 1. As discussed above, Bane fails to teach or suggest, either expressly or inherently, all the features of claim 1.

Freedman et al. relates to a structure having adjoining pressure sensitive adhesive strata, where the outermost strata has a different adhesion to a substrate. Freedman et al., however, fails to make up for Bane's deficiencies. While Freedman et al. may teach that particular materials may be used as the substrate, the Examiner has not provided any technical reasons why such materials are necessarily moisture resistant. Further, even though Freedman et al. may employ removable adhesives, the

Examiner has not provided any basis in fact or technical reasoning as to why such removable adhesives necessarily have a Moist Loop Tack as recited in the claims. Again, the fact that a particular material could have a particular characteristic is not sufficient to establish inherency. Rather, the Examiner must provide a basis in fact or technical reason that the missing characteristic is necessarily present and could be recognized by persons skilled in the art as being necessarily present.

Therefore, the combination of Bane and Freedman fail to teach or suggest, either expressly or inherently, all the features of the claims. Consequently, the combination of Bane and Freeman fails to render claims 5-7 obvious. Applicant requests that the rejection be reversed.

D. The rejection of claims 2-4, and 6-7 under 35 U.S.C. §103(a).

The Examiner's Rejection:

Claims 2-4 and 6-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over McClintock (US 5,217,307) as applied to claim 1, and further in view of Freedman et al. (US 4,543,139).

Regarding claims 2-4 and 6-7, the Examiner contends that

McClintock does not teach a substrate comprising a polymer coated paper face stock, a multilayer, or a polyolefin film.

Freedman teaches an adhesive tape for use on a substrate that is a polymer coated paper, or a polymer such as polypropylene and polyesters including polyethylene terephthalate (see col. 4, ln. 57-58; col. 5, ln. 11-20).

Therefore, it would have been obvious to one of ordinary skill in the art to have employed the substrate, as taught by Freedman, in the adhesive article of McClintock. Since Freedman teaches the use of a substrate made of polypropylene and polyethylene terephthalate as well as polymer-coated paper as alternatives of each other, the use of one or another would have been dependent upon user's preference and intended use.

Appellant's Response

The combination of McClintock and Freedman et al. fails to render the claims obvious. As discussed above with respect to the rejections under § 102, McClintock fails to teach or suggest all the features of claims 1, from which claim 2-4 and 6-7 depend. Freedman et al. was also discussed above. As discussed above, the

Examiner has not provided any technical reasons or basis in fact to show that the materials disclosed in Freedman et al. are necessarily moisture resistant and/or have the recited Moist Loop Tack. Consequently, the Examiner has not shown how the art discloses or suggests an article as set forth in the claims. Applicant requests that the rejection be withdrawn.

E. The rejection of claims 2-4, and 6-7 under 35 U.S.C. §103(a).

The Examiner's Rejection:

Claims 5-11, 19-20, and 46-48 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bane (US 5,366,087) as applied to claim 1 and claim 43, and further in view of van Driesten et al. (WO 00/46316).

Regarding claims 5-11, 19-20, and 46-48, the Examiner contends that

Bane is as set forth in claims 1 and 43 above and incorporated herein. Bane does not teach the substrate or the adhesive as recited in the instant claims.

Van Driesten (WO '316) discloses an adhesive article, comprising a face construct 11, a release layer 13, a pressure-sensitive adhesive (permanent) layer 14, a polyester layer 15, a pressure-sensitive layer 12, a non pressure sensitive layer 2, a release layer 32, a liner layer 37, a pressure sensitive layer 36, a release layer 33, and a liner layer 31 (see claims 1-23; Fig. 14A).

Layers 11, 31, and 37 are made of paper and plastic film of a polyolefin, such as polyethylene and polypropylene, or a polyester, such as polyethylene terephthalate (see claims 19-21; page 15, 2nd paragraph). The PSA adhesive and non-PSA adhesive can be hotmelt adhesive and rubber-based or acrylic-based (see page 9, ln. 21-33; page 11, ln. 24-37; page 19, ln. 23-36).

Therefore, it would have been obvious to one of ordinary skill in the art to have employed the substrate and the adhesive, as taught by Van Driesten, in the laminate of Bane. Since Van Driesten teaches the substrate to be paper, polyolefin, or polyester, the use of one or another would have been dependent upon user's preference and intended use. The same argument is presented with the use of the hotmelt adhesive as the alternative of the rubber-based or acrylic-based adhesive and PSA or non-PSA adhesive.

Appellant's Response

Van Driesten is directed to a dry peel label that includes a non-PSA layer. Even though Van Driesten may teach particular materials as being suitable for use in the non-PSA layer, Van Driesten does not teach or suggest that such materials have a particular

tack and also fails to provide any indication that such materials would necessarily have a particular tack value. Again, the fact that a particular material could have a particular characteristic is not sufficient to establish inherency. Rather, the Examiner must provide a basis in fact or technical reason that the missing characteristic is necessarily present and could be recognized by persons skilled in the art as being necessarily present. Consequently, the Examiner has not established that the combination of Bane and Van Driesten teach or suggest every feature set forth in the claims. As such the Examiner has failed to establish a *prima facie* case of obviousness. (See *Ex parte Alexander*.) Appellant requests that the rejection based on Bane and Van Driesten be reversed.

F. The rejection of claims 2-4, 6-7, and 9-10 under 35 U.S.C. §103(a).

The Examiner's Rejection:

Claims 2-4, 6-7, and 9-10 have been rejected under 35 U.S.C. §103(a) as being unpatentable over McClintock (US 5,217,307) as applied to claim 1, and further in view of van Driesten et al. (WO 00/46316).

Regarding claims 2-4, 6-7, and 9-10, the Examiner contends that

McClintock does not teach the substrate or the adhesive as recited in the instant claims.

Van Driesten (WO '316) discloses an adhesive article, comprising a face construct 11, a release layer 13, a pressure-sensitive adhesive (permanent) layer 14, a polyester layer 15, a pressure-sensitive adhesive layer 12, a non pressure sensitive layer 2, a release layer 32, a liner layer 37, a pressure sensitive adhesive layer 36, a release layer 33, and a liner layer 31 (see claims 1-23; Fig. 14A).

Layers 11, 31, and 37 are made of paper and plastic film of a polyolefin, such as polyethylene and polypropylene, or a polyester, such as polyethylene terephthalate (see claims 19-21; page 15, 2nd paragraph). The PSA adhesive and non-PSA adhesive can be hotmelt adhesive and rubber-based or acrylic-based (see page 9, ln. 21-33; page 11, ln. 24-37; page 19, ln. 23-36).

Therefore, it would have been obvious to one of ordinary skill in the art to have employed the substrate and adhesive, as taught by Van Driesten, in the laminate of McClintock. Since Van Driesten teaches the substrate to be paper, polyolefin, or polyester, the use of one or another would have been dependent upon user's preference and intended use. The same argument is presented with

the use of the hotmelt adhesive as the alternative of the rubber-based or acrylic-based adhesive and PSA or non-PSA adhesive.

Appellant's Response

McClintock and Van Driesten have been discussed above. Again, even though Van Driesten may teach particular materials as being suitable for use in the non-PSA layer, Van Driesten does not teach or suggest that such materials have a particular tack and also fails to provide any indication that such materials would necessarily have a particular tack value. And, the fact that a particular material could have a particular characteristic is not sufficient to establish inherency. Consequently, the Examiner has not shown that Van Driesten makes up for McClintock's deficiencies, and has failed to show that the combination of McClintock and Van Driesten teach or suggest every feature set forth in the claims. As such the Examiner has failed to establish a *prima facie* case of obviousness. Appellant requests that the rejection based on Bane and Van Driesten be reversed.

VIII. CONCLUSION

For the foregoing reasons, the honorable Board is requested to reverse the Examiner's rejection of all of the claims pending in the application and to allow these claims.

If any additional fees are required for the filing of this paper, the Commissioner is authorized to charge those fees to Deposit Account #18-0988 (Docket No. AVERP3447USA).

Respectfully submitted,
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Attachment: Exhibit A

APPENDIX

CLAIMS SUBJECT TO APPEAL

1. An adhesive article comprising (a) a moisture resistant substrate having a first and second surface, (b) a removable and resealable adhesive adhered to at least a first portion of the first surface of the substrate, and (c) a permanent adhesive adhered to at least a second portion of the first surface of the substrate; wherein the removable adhesive is removable and resealable in the presence of moisture from refrigerated or frozen food packaging environments and has a Moist Loop Test result of at least about 0.8 N/25mm at a test plate temperature of 5°C.
2. The article of claim 1 wherein the moisture resistant substrate comprises a polymer coated paper facestock.
3. The article of claim 1 wherein the moisture resistant substrate comprises a monolayer or multilayer polymeric film.
4. The article of claim 1 wherein the substrate comprises a multilayer film.
5. The article of claim 1 wherein the substrate comprises a film selected from polystyrenes, polyolefins, polyamides, polyesters, polycarbonates, polyurethanes, polyacrylates, polyvinyl alcohol, poly(ethylene vinyl alcohol), poly(alkylene vinyl acetates), poly(alkylene acrylates), ionomers, and mixtures thereof.
6. The article of claim 1 wherein the substrate comprises a polyolefin film.
7. The article of claim 1 wherein the substrate comprises an ethylene or propylene polymer or copolymer.

8. The article of claim 1 wherein the removable adhesive comprises an acrylic based pressure sensitive adhesive.

9. The article of claim 1 wherein the removable adhesive comprises a UV curable hot melt acrylic adhesive.

10. The article of claim 1 where the removable adhesive comprises a hot melt pressure sensitive adhesive.

11. The article of claim 1 wherein the removable adhesive comprises a rubber based adhesive.

19. The article of claim 1 wherein the permanent adhesive comprises a rubber based adhesive, an acrylic adhesive, a vinyl ether adhesive, a silicone adhesive, or mixtures of two or more thereof.

20. The article of claim 1 wherein the permanent adhesive comprises an acrylic based or rubber based pressure sensitive adhesive.

41. A sheet of adhesive closures comprising:
a carrier sheet having a release surface; and
a plurality of adhesive articles releasably adhered to the release surface of the sheet, each article comprising (a) a moisture resistant substrate having a first and second surface, (b) a removable and resealable adhesive adhered to at least a first portion of the first surface of the substrate, and (c) a permanent adhesive adhered to at least a second portion of the first surface of the substrate; wherein the removable adhesive is removable and resealable in the presence of moisture from refrigerated or frozen food packaging environments and has a Moist Loop Test result of at least about 0.8 N/25mm at a test plate temperature of 5°C.

43. A roll of adhesive closures comprising:

a wound carrier having a release surface; and

a plurality of adhesive articles releasably adhered to the release surface of wound carrier, each article comprising (a) a moisture resistant substrate having a first and second surface, (b) a removable and resealable adhesive adhered to at least a first portion of the first surface of the substrate, and (c) a permanent adhesive adhered to at least a second portion of the first surface of the substrate; wherein the removable adhesive is removable and resealable in the presence of moisture from refrigerated or frozen food packaging environments and has a Moist Loop Test result of at least about 0.8 N/25mm at a test plate temperature of 5°C.

45. The adhesive article of claim 1 wherein the removable and resealable adhesive is removable and resealable at temperatures within the range of from about 10°C to about -30°C.

46. The adhesive article of claim 41 wherein the permanent adhesive comprises a rubber based adhesive, an acrylic adhesive, a vinyl ether adhesive, a silicone adhesive, or mixtures of two or more thereof.

47. The adhesive article of claim 41 wherein the permanent adhesive comprises an acrylic based or rubber based pressure sensitive adhesive.

48. The adhesive article of claim 41 wherein the removable adhesive comprises a UV curable hot melt acrylic adhesive.

APPENDIX

EVIDENCE

None

APPENDIX

RELATED PROCEEDINGS

None

**[2] Patentability/Validity — Anticipation
— Identity of elements (§ 115.0704)**

Claims in application directed to composition for embolizing aneurisms were improperly rejected for anticipation, since none of prior art references cited by examiner expressly describes composition having viscosity of at least 150 centiStokes at 40 degrees C, as required by claims in application, since examiner contends that prior art compositions contain similar components used in overlapping ranges of concentrations, but mere possibility that some prior art composition might have viscosity required by claims in application is not adequate to support finding of inherent anticipation, and since examiner thus has not provided evidence or scientific reasoning to show that cited prior art discloses composition that expressly or inherently meets all limitations of claims at issue.

**[3] Patentability/Validity — Obviousness
— Relevant prior art — Particular inventions (§ 115.0903.03)**

Discovery of optimum value for variable in known process is not obvious if optimized parameter was not recognized in prior art as one that would affect results; in present case, claims in application directed to composition for embolizing aneurisms were improperly rejected for obviousness, since claims require composition to have viscosity of at least 150 centiStokes at 40 degrees C, since references cited by examiner, rather than suggesting that prior art compositions could be "optimized" by increasing their viscosity to level recited in claims, instead teach that low viscosity is desirable characteristic of embolic compositions, and since, therefore, none of cited references would have led person of ordinary skill in art to modify known embolic compositions by increasing their viscosity to level required by claims at issue.

**[4] Patentability/Validity — Obviousness
— Evidence of (§ 115.0906)**

In case in which prior art teaches away from chemical composition recited in claims, obviousness cannot be proved merely by showing that known composition could have been modified by routine experimentation, or solely on expectation of success; instead, it must be shown that those of ordinary skill in art would have had some apparent reason to

Ex parte Whalen**U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences**

Appeal No. 2007-4423

Decided July 23, 2008

PATENTS**[1] Patentability/Validity — Anticipation
— Double patenting (§ 115.0708)**

Claims in application directed to composition for embolizing aneurisms were improperly rejected for obviousness-type double patenting, since there is no evidence that any compositions encompassed by claims of applicants' existing patents, which are limited to compositions containing less than about eight weight percent polymer, would have viscosity of 150 centiStokes at 40 degrees C, as required by claims in application, and application claims thus are not anticipated by existing patents, and since examiner has not presented any other explanation supported by record to justify conclusion that compositions of claims at issue are obvious variants of compositions claimed in existing patents.

modify known composition in manner that would result in claimed composition.

Patent application of Thomas J. Whalen II, Chinh N. Tran, Noah M. Roth, and Richard J. Greff (No. 10/281,142). Applicants appeal from rejection of claims on grounds of anticipation, obviousness, and obviousness-type double patenting. Reversed.

Before Fleming, chief administrative patent judge, and Lane, Grimes, Lebovitz, and Prats, administrative patent judges.

Grimes, J.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition for embolizing an aneurysm, which the Examiner has rejected for anticipation, obviousness, and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification states that "[e]mbolizing compositions (embolic compositions) heretofore disclosed in the art include those comprising a biocompatible polymer, a biocompatible solvent and a contrast agent which allowed visualization of the *in vivo* delivery of the composition" (Spec. 3). "Such compositions typically contain no more than about 8 weight percent of biocompatible polymer based on the weight of the total composition" (*id.*).

The Specification states that prior art embolic compositions had the drawback that "upon ejection of the embolic composition in a vascular site, the coherent mass subsequently formed was often distal and not proximate the ejection port of the catheter. Moreover, upon solidification, the solid mass formed was often linear in shape (i.e., having a 'string shape')." (*Id.*) This property of the prior art compositions is said to lead to difficulty in sitespecific delivery of the embolic composition, and the danger that fragments of the solidified composition will embolize an artery or "lodg[e]" at undesired locations in the vasculature" (*id.*).

The Specification discloses that "formation of a solid non-migratory mass having a sub-

stantially contiguous or 'ball' shape can be achieved by use of embolic compositions . . . [having] a viscosity of at least 150 cSt at 40° C" (*id.*).¹ According to the Specification, "the viscosity of these compositions is significantly higher than those containing 8 weight percent polymer, thereby rendering it difficult to employ conventional delivery means (e.g., syringe). . . . However, delivery means such as the threaded syringes described [in two provisional patent applications] now renders the use of these highly viscous compositions practical." (*Id.* at 4.)

Claims 1-17 are pending and on appeal. Claim 1 is representative and reads as follows:

1. A composition capable of embolizing an aneurysm at a vascular site comprising:

- (a) a biocompatible polymer;
- (b) a biocompatible contrast agent wherein a sufficient amount of said contrast agent is employed in said composition to effect visualization *in vivo*; and
- (c) a biocompatible solvent which solubilizes said biocompatible polymer

wherein a sufficient amount of said polymer are [sic] employed in said composition such that, upon delivery to a vascular site, a polymer precipitate forms which embolizes said vascular site; and

further wherein the biocompatible polymer has a molecular weight sufficient to impart to the composition a viscosity of at least about 150 cSt at 40° C.

The components recited in claim 1 — biocompatible polymer, biocompatible contrast agent, and biocompatible solvent — are the same as those in known embolic compositions (Spec. 3). Thus, if claim 1 differs from the prior art, it is by virtue of the limitation that "the biocompatible polymer has a molecular weight sufficient to impart to the composition a viscosity of at least about 150 cSt at 40° C." Claim 2, the only other independent claim on appeal, also includes this limitation.

As we interpret it, this limitation requires only that the claimed composition have "a viscosity of at least about 150 cSt at 40° C." Although the claim also refers to the molecular weight of the polymer in the composition,

¹ Viscosity can be measured in units of centiStokes (cSt) or centipoise (App. Br. 6).

that reference does not limit the claim: If a composition comprises the recited polymer and has the recited viscosity, then the polymer necessarily "has a molecular weight sufficient to impart" the resulting viscosity, at whatever concentration of polymer is present.

The Examiner has rejected the claims as follows:

- Claims 1-17 stand rejected for obviousness-type double patenting based on claims 1-5 of Greff '568,² claims 1-46 of Evans,³ claims 1-6 of Greff '508,⁴ and claims 1-6 of Greff '767;⁵
- Claims 1-13 and 15-17 stand rejected under 35 U.S.C. § 103 as obvious in view of Evans;
- Claims 1-17 stand rejected under 35 U.S.C. § 103 as obvious in view of Greff '767; and
- Claims 1-6, 9, 10, and 14-17 stand rejected under 35 U.S.C. §§ 102(b) or 103 as anticipated by or obvious in view of Toki.⁶

DOUBLE PATENTING

The Double Patenting Issue

Claims 1-17 stand rejected for obviousness-type double patenting based on claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, and claims 1-6 of Greff '767.⁷ The Examiner's position is:

both the patented claims and the instant pending claims are directed to compositions comprising a biocompatible polymer, a biocompatible contrast agent and a biocompatible solvent. Therefore, each set of the patented claim[s] anticipates the scope of the pending claim[s]. Accordingly, it would have been obvious to one of ordinary skill

in the art at the time of invention to practice the pending claims when in possession of the patented claims. Thus, the pending claims are obvious variants of the patented claims.

(Ans. 4.)

Appellants contend that "[t]here is no teaching of viscosity in any of Claim 1-5 of the '568 patent" (App. Br. 11); "[t]here is no teaching, in either the specification or the claims of [Evans], of viscosities of 150 centiStokes at 40°C" (*id.* at 12); "it is unclear why Claims 1-17 [sic] of [Greff '508] would motivate one skilled in the art to make and use the high viscosity embolic composition of the claims on Appeal" (*id.* at 13); and "for the same reasons noted for the '508 patent, the rejection of Claims 1-17 ... over Claims 1-6 of the '767 patent is in error" (*id.*).

In view of these conflicting positions, the double-patenting issue presented is: Are the rejected claims directed to a composition that is an obvious variant of the compositions claimed in Greff '568, Evans, Greff '508, or Greff '767?

Findings of Fact Relating to Double Patenting

FF1. Claim 1 of Greff '568 is directed to a composition comprising:

- (a) from about 2.5 to about 8 weight percent of a cellulose diacetate having an acetyl content of from about 31 to about 40 weight percent;
- (b) from about 10 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;
- (c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of the cellulose diacetate, water insoluble contrast agent and biocompatible solvent is based on the total weight of the complete composition.

(Greff '568, col. 9, ll. 37-50.)

FF2. Claim 1 of Evans is directed to a composition comprising:

- (a) from about 2.5 to about 8.0 weight percent of a biocompatible polymer;
- (b) from about 10 to about 40 weight percent of a water insoluble, biocompatible contrast

² Greff et al., U.S. Patent 5,580,568, issued Dec. 3, 1996.

³ Evans et al., U.S. Patent 5,695,480, issued Dec. 9, 1997.

⁴ Greff et al., U.S. Patent 5,581,508, issued Dec. 22, 1998.

⁵ Greff et al., U.S. Patent 5,667,767, issued Sept. 16, 1997.

⁶ Toki et al., "A new liquid material for embolization of arteriovenous malformations," 11 *AJNR, Amer. Journal of Neuroradiology* 163 (1990).

⁷ In the Answer, the Examiner also rejected claims 1-17 based on claims 1-15 of U.S. Patent 6,531,111 (Ans. 4). However, Appellants have filed a terminal disclaimer with respect to the '111 patent (terminal disclaimer received July 19, 2004) so that basis of the rejection has been overcome.

agent having an average particle size of about 10 m or less; and

- (c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of the polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition.

(Evans, col. 11, ll. 47-58.)

FF3. Claim 1 of Greff '508 is directed to a composition comprising:

- (a) from about 2.5 to about 8.0 weight percent of an ethylene vinyl alcohol copolymer;
- (b) from about 20 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;
- (c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of each of the components is based on the total weight of the complete composition.

(Greff '508, col. 10, ll. 7-16.)

FF4. Claim 1 of Greff '767 is directed to a composition comprising:

- (a) from about 2.5 to about 8.0 weight percent of an ethylene vinyl alcohol copolymer;
- (b) from about 10 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;
- (c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of each of the components is based on the total weight of the complete composition.

(Greff '767, col. 9, ll. 37-50.)

FF5. Claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, and claims 1-6 of Greff '767 do not limit the claimed compositions to those having a particular viscosity, and therefore encompass compositions having the components recited in those claims, in the recited concentrations, regardless of the viscosity of the resulting compositions.

FF6. The Examiner has not pointed to any evidence showing that any composition encompassed by claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or

claims 1-6 of Greff '767 would inherently have a viscosity of at least about 150 cSt at 40° C.

Discussion of the Double Patenting Issue

We conclude that the Examiner has not shown that the composition of the claims on appeal is an obvious variant of the compositions of claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or claims 1-6 of Greff '767.

The analyses for obviousness under 35 U.S.C. § 103 and obviousness-type double patenting are not identical; for one thing, "[t]he objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 n.1 [68 USPQ2d 1865] (Fed. Cir. 2003). The purpose of an obviousness-type double patenting rejection is "to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later." *In re Berg*, 140 F.3d 1428, 1431 [46 USPQ2d 1226] (Fed. Cir. 1998).

[1] Here, all of the claims cited by the Examiner are limited to compositions containing less than about 8 weight percent polymer (FF1 to FF4). The instant Specification states that known embolic compositions typically contained less than about 8 weight percent polymer (Spec. 3) and that such compositions often formed undesirable "string shaped" masses (*id.*).

The Examiner has not directed us to evidence sufficient to show that any composition encompassed by the relied-upon patented claims — with less than about 8 weight percent polymer — would have a viscosity of 150 cSt at 40° C. Therefore, the Examiner's finding that the relied-upon patented claims anticipate the claims on appeal is not supported by the evidence.

The Examiner has not provided any other reasoned, fact-based explanation supported by the evidence of record to justify a conclusion that the compositions defined by the claims on appeal are obvious variants of the compositions of claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or claims 1-6 of Greff '767. We therefore reverse the re-

jections for obviousness-type double patenting.

REJECTIONS BASED ON THE PRIOR ART

The Obviousness and 102(b)/103 Issues

The Examiner finds that the compositions taught by Evans and Taki "inherently possess the same viscosity" as the claimed composition because they "comprise similar components[s] used in overlapping ranges of concentrations as those claimed" (Ans. 5-6; see also *id.* at 7). Alternatively, the Examiner concludes that the claimed compositions would have been obvious in view of the compositions taught by Evans, Greff '767, and Taki because "it would have been *prima facie* obvious to optimize the viscosity range of [the known] compositions by routine experimentation" (*id.* at 6, 7).

Appellants argue that Evans, Greff '767, and Taki refer to viscosity only in passing and when they do, they indicate that the disclosed compositions should have a viscosity well under 150 cSt (Evans and Greff '767) or are of "low viscosity" (Taki) and it is "unclear why [the prior art disclosures] would motivate one skilled in the art to make and use [a] high viscosity embolic composition" (App. Br. 12, 13-14, 15-16).

In view of these conflicting positions, the issue presented with respect to patentability over the cited prior art is: Do the disclosures of Evans, Greff '767, or Taki anticipate, or would they have rendered obvious, the claimed compositions to those of ordinary skill in the art?

Findings of Fact Relating to the Prior Art Rejections

FF7. The Examiner finds that "Evans' compositions have a viscosity of less than 60 centipoise at 20° C (see col 5, lines 37-43). Accordingly, Evans anticipates the limitations of the instant claims." (Ans. 5.)

FF8. The Examiner finds that "[a]lthough Evans does not specifically recite the instantly claimed viscosity of 150 cSt at 40° C . . . , Examiner takes the position that compositions disclosed by Evans inherently possess the same viscosity . . . as the instantly claimed invention, because Evans' compositions comprise similar component[s] used in overlapping ranges of concentrations" (Ans. 5-6).

FF9. The Examiner finds that a person of ordinary skill in the art "would have been motivated to optimize the viscosity of the Evans' final formulation, because he would have had a reasonable expectation of success in achieving the safest clinical outcome and avoiding transvenous passage" of the embolizing composition (Ans. 6).

FF10. The Examiner relies on the same reasoning in the rejections based on Greff '767 and Taki (Ans. 6-8).

FF11. Evans teaches compositions comprising a biocompatible polymer (2.5-8 wt %), a biocompatible contrast agent (10-40 wt %), and a biocompatible solvent (52-87.5 wt %) (Evans, col. 3, ll. 32-43).

FF12. Evans teaches that one preferred composition "has a viscosity equal to or less than 60 centipoise at 20° C" (Evans, col. 5, ll. 39-43).

FF13. According to Appellants, units of poise (or centipoise) are related to units of Stokes (or centiStokes) according to the equation $\text{Poise} = \text{Stokes} \times \text{density}$ (App. Br. 6).

FF14. The Examiner has not disputed that $\text{Poise} = \text{Stokes} \times \text{density}$.

FF15. According to Appellants, "[f]or Newtonian fluids, it is well understood that viscosity decreases as temperature increases" (App. Br. 7).

FF16. The Examiner has not disputed that viscosity decreases as temperature increases.

FF17. Evans discloses that "all other factors being equal, copolymers having a lower molecular weight will impart a lower viscosity to the composition as compared to higher molecular weight copolymers. Accordingly, adjustment of the viscosity of the composition as necessary for catheter delivery can be readily achieved by mere adjustment of the molecular weight of the copolymer composition." (Evans, col. 5, ll. 44-50.)

FF18. Greff '767 teaches compositions comprising an ethylene vinyl alcohol copolymer (2.5-8 wt %), a contrast agent that is tantalum, tantalum oxide or barium sulfate (10-40 wt %), and a biocompatible solvent (52-87.5 wt %) (Greff '767, col. 3, ll. 37-48).

FF19. Greff '767 teaches that a composition comprising 6.8 weight percent of ethylene vinyl alcohol copolymer ("EVOH") in dimethyl sulfoxide ("DMSO") has a viscosity of approximately 60 centipoise at 20° C (Greff '767, col. 9, ll. 28-31).

FF20. Greff '767 teaches that addition of 38.5 weight percent metrizamide (a contrast agent; Greff '767, col: 9, ll. 4-6) to the composition of FF19 increased its viscosity to approximately 145 centipoise at 20° C (*id.* at col. 9, ll. 31-34).

FF21. Greff '767 teaches that addition of 35 weight percent tantalum or barium sulfate to a composition similar to that of FF19 did not materially alter its viscosity (Greff '767, col. 9, ll. 35-37).

FF22. Greff '767 states that the purpose of the compositions referred to in FF19 to FF21 was to "illustrate that certain embolizing agent/contrast agent combinations provide for physical properties which make injection of the combination into vascular sites significantly more difficult" (Greff '767, col. 9, ll. 24-27).

FF23. Taki teaches an embolizing composition containing "5 g of solid ethylene vinyl alcohol copolymer (EVAL) and 35 g of powder metrizamide dissolved in 60 g of dimethyl sulfoxide (DMSO) as a solvent" (Taki 163).

FF24. Taki teaches that the "EVAL and DMSO mixture was of low viscosity and could be easily injected through the narrow lumen of the microballoon catheter, which was 150 cm in length" (Taki 168).

Discussion of the Obviousness and 102(b)/103 Issues

[2] We determine that the Examiner has not made out a *prima facie* case that the claimed compositions are anticipated by Taki or would have been obvious in view of any of Evans, Greff '767, or Taki.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 [2 USPQ2d 1051] (Fed. Cir. 1987). None of the references relied on by the Examiner expressly describes an embolizing composition having a viscosity of at least 150 cSt at 40° C as required by claim 1.

The Examiner has not provided an adequate basis — based on evidence or scientific reasoning — to support the finding that the "compositions disclosed by Evans inherently possess the same viscosity . . . as the instantly claimed invention" (FF8, Ans. 5-6). The Examiner reasons that "Evans' compositions comprise similar component[s] used in over-

lapping ranges of concentrations," but even if some of the compositions encompassed by Evans' broad disclosure might have a viscosity of 150 cSt at 40° C, that possibility is not adequate to support a finding of inherent anticipation.

"Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 [212 USPQ 323] (CCPA 1981). *See also Ex parte Skinner*, 2 USPQ2d 1788, 1789 (BPAI 1986) ("[T]he examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to the applicant to disprove the inherency.).

The Examiner has not provided evidence or scientific reasoning to show that any specific composition disclosed by Evans is within the scope of the instant claims, and therefore has not made out a case of inherent anticipation by Evans. The Examiner's finding that "Evans anticipates the limitations of the instant claims" (FF7, Ans. 5) is not supported by the evidence of record. The Examiner also has not shown that Taki discloses a composition that expressly or inherently meets all the limitations of the instant claims. We therefore reverse the rejection for anticipation based on Taki.

The Examiner's obviousness rejections are based on the reasoning that a person of ordinary skill in the art "would have been motivated to optimize the viscosity of the Evans' [and Greff '767's and Taki's] final formulation[s], because he would have had a reasonable expectation of success in achieving the safest clinical outcome and avoiding transvenous passage" of the embolizing composition (FF9, FF10; Ans. 6-8).

[3] The Examiner has not made out a *prima facie* case that the claimed compositions would have been obvious based on the teachings of Evans, Greff '767, or Taki. While "the discovery of an optimum value of a variable in a known process is normally obvious," *In re Antonie*, 559 F.2d 618, 620 [195 USPQ 6] (CCPA 1977), this is not always the case. One exception to the rule is where the parameter optimized was not recognized in the prior art as one that would affect the results. *Id.*

Here, the Examiner has not pointed to any teaching in the cited references, or provided any explanation based on scientific reasoning, that would support the conclusion that those skilled in the art would have considered it obvious to "optimize" the prior art compositions by increasing their viscosity to the level recited in the claims. No reason to have done so is apparent to us based on the record. On the contrary, the references all suggest that low viscosity was a desired property in embolic compositions. Evans teaches that a preferred composition has a viscosity of 60 centipoise or less at 20° C (FF12). Appellants calculate, and the Examiner does not dispute, that 60 centipoise at 20° C corresponds to less than 75 cSt at 40° C (App. Br. 12). Therefore, Evans' preferred composition has a viscosity less than half of that required by the instant claims.

Likewise, Greff '767 teaches that a composition with a viscosity of 145 cSt at 20° C had "physical properties which make[] injection ... into vascular sites significantly more difficult" (FF20, FF22) — and the only physical property of the composition discussed is its viscosity. In agreement with the other references, Taki teaches that its composition had a low viscosity (FF24) and had the desirable property of being easily injected through a microballoon catheter (FF24).

Thus, the references teach that low viscosity is a desirable characteristic for embolic compositions. In our view, none of the cited references would have led a person of ordinary skill in the art to modify the known embolic compositions by increasing their viscosity to at least 150 cSt at 40° C. The Examiner has not adequately explained why such a modification would have been obvious.

The U.S. Supreme Court recently held that rigid and mandatory application of the "teaching-suggestion-motivation," or TSM, test is incompatible with its precedents. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 [82 USPQ2d 1385] (2007). The Court did not, however, discard the TSM test completely; it noted that its precedents show that an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.*

The Court held that the TSM test must be applied flexibly, and take into account a number of factors "in order to determine whether there was an apparent reason to combine the

known elements in the fashion claimed." *Id.* at 1740-41. Despite this flexibility, however, the Court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does." *Id.* "To facilitate review, this analysis should be made explicit." *Id.*

[4] The obviousness rationale addressed in *KSR* was premised on combining elements known in the prior art. *Id.* at 1738-39. A parallel analysis applies, however, to a rejection premised on the obviousness of modifying a known composition to change its properties.

The *KSR* Court noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed." *Id.* at 1741.

In the same way, when the prior art teaches away from the claimed solution as presented here (FF12, FF20, FF22 and FF 24), obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition.

The Examiner has not persuasively explained why a person of ordinary skill in the art would have had a reason to modify the compositions taught by Evans, Greff '767, or Taki in a way that would result in the compositions defined by the claims on appeal. Therefore, the Examiner has not made out a *prima facie* case of obviousness under 35 U.S.C. § 103. We reverse the rejections of claims 1-13 and 15-17 as obvious in view of Evans; the rejection of claims 1-17 as obvious in view of Greff '767; and the rejection of claims 1-6, 9, 10, and 14-17 as anticipated by or obvious in view of Taki.

SUMMARY

The rejections on appeal are not supported by a preponderance of the evidence in the record and are therefore reversed.

REVERSED